

Paper #    Attach.

EAST Version 1.03.0002

search date: 4 March 2002

Application: 09/680,738

BRS	L1	886	"yeast two hybrid" or "yeast two-hybrid" or "interaction trap"
BRS	L6	2	inducible with 1
BRS	L11	150	steroid and 1
BRS	L16	4	steroid same 1



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Washington, DC 20503  
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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 680,738	10 06 2000	David N. Edwards	HYB775-00 00381A	2494

21003 7590 03 11 2002

BAKER & BOTTS  
30 ROCKEFELLER PLAZA  
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EXAMINER

LOEB, BRONWEN

ARTICLE PAPER NUMBER

DATE MAILED: 03 11 2002

12

Please find below and or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/680,738

Examiner

Bronwen M. Loeb

Applicant(s)

EDWARDS ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,8-13 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-6, 8-13 and 16-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 October 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This action is in response to the amendment filed 12 December 2001 in which claims 1, 4, 5, 8, 9, 11, 12, 16 and 17 were amended, claims 3, 7, 14 and 15 were cancelled and new claims 18-21 were presented.

Claims 1, 2, 4-6, 8-13 and 16-21 are pending.

### ***Drawings***

1. The proposed drawing correction with respect to Fig. 3 filed on 12 December 2001 has been disapproved because it is not in the form of a pen-and-ink sketch showing changes in red ink or with the changes otherwise highlighted. See MPEP § 608.02(v).
2. No proposed drawing correction was received with respect to the objection to Fig. 1 made of record in the Action mailed 1 August 2001. The objection is therefore maintained.
3. Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect may be deferred until after the examiner has considered the proposed drawing correction. Failure to timely submit the proposed drawing correction will result in the abandonment of the application.

### ***Response to Amendment***

4. The rejection of claims 1-16 under 35 U.S.C. §112, first paragraph, for lack of enablement has been withdrawn in view of Applicant's amendment.

The rejection of claims 1-9 under 35 U.S.C. §102(b) as being anticipated by Finley et al ("Two-hybrid analysis of genetic regulatory networks" in The Yeast Two-Hybrid System, Bartel et al eds. 1997 Oxford University Press pp. 197-214) has been withdrawn in view of Applicant's amendment.

The rejection of claims 1-15 under 35 U.S.C. 103(a) as being unpatentable over Finley et al, in view of Schena et al (Methods in Enzymology (1991) 194:389-398) has been withdrawn in view of Applicant's amendment.

5. Claims 12, 13 and 16, and newly-presented claims 18-21, stand rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record and as further discussed below.

Claims 1, 2, 4-6, 8-13, 16 and 17, and newly-presented claims 18-21, stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for reasons of record and as further discussed below.

### ***Response to Arguments***

6. With regard to the rejection of claims 12, 13 and 16, and newly-presented claims 18-21, under 35 USC §112, first paragraph for insufficient written description, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant argues that any small molecule suitable for use as modulatory agents would be apparent to one of skill in the art and one of skill in the art would be readily

able to peruse the literature and determine which cellular pathways and small molecules are appropriate for a given two-hybrid experiment. First, while one of skill in the art may be able to peruse the literature to identify small molecules for use in the claimed invention, this assertion is more germane to enablement, not to written description. As set forth in the Action mailed 1 August 2001, the specification does not define in structural detail or provide specific examples of small molecules, steroid analogues, steroid mimics, membrane-active agents, membrane-active analogues, small molecular pharmaceutical agents or biomolecule or natural or synthetic biopharmaceuticals. While the desired function is disclosed for the genres as a whole (modulating amount of first or second hybrid by acting at one or more of an extracellular, membrane, intracellular or nuclear site), there is no disclosure of specific structural elements corresponding to the desired function for each generic class to indicate that Applicant had possession of the genres. The rejection is maintained.

7. With regard to the rejection of claims 1, 2, 4-6, 8-13, 16 and 17, and newly-presented claims 18-21, under 35 USC §112, second paragraph, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant states that claim 1 was amended so that the preamble better relates to the steps of the claim. This argument is not persuasive as the preamble states "detecting an interaction between a first test protein and a second test protein" while the method steps recited lead to determining the extent to which the detectable reporter gene is activated. This rejection would be overcome by amending claim 1 at the end of

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step (d) to recite "whereby an interaction between the first test protein and the second test protein is detected".

### **Conclusion**

Claims 1, 2, 4-6, 8-13 and 16-21 are rejected. Claims 1, 2, 4-6, 8-13 and 16-21 are free of prior art.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 10:00 AM to 6:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Tracey Johnson, Patent Analyst whose telephone number is (703) 305-2982.

Bronwen M. Loeb, Ph.D.  
Patent Examiner  
Art Unit 1636

March 10, 2002

  
**REMY YUCEL, PH.D**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**